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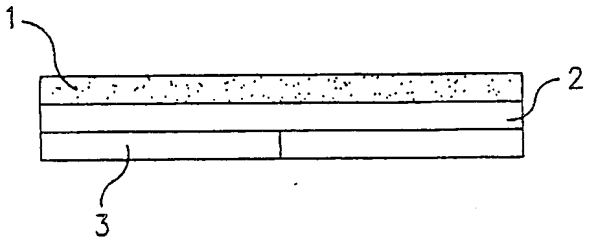
(57) Abstract



A method is provided for treatment of a condition of an epithelium of a subject, the condition is for example inflammation, insect bite, allergic reaction burn, sun burn, eczema, edema, acne, dry skin, oily skin, malodor, abrasion, incision, and bruise, the method comprising applying proximate to the epithelium of the subject a device for cosmetic aromatherapy treatment of the subject, including an aromatherapeutic composition in a polymeric matrix, the device having a skin adhesive. In another embodiment a composition is provided for aromatherapy, comprising an essential oil in a polymeric matrix in a container with a suitable vehicle, such that upon delivery of the composition from the container and application to the skin of a subject, evaporative loss of the vehicle from the composition results in formation of a film.

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TRANSDERMAL DEVICES COMPRISING ESSENTIAL OILS FOR AROMATHERAPY

Technical Field

This invention is directed to methods, compositions, and devices for the topical and prolonged delivery of aromatherapeutic agents.

Background of the Invention

A number of different approaches are available for delivering active agents to a predetermined target site in the body. For example, delivery by ingestion results in a formulation that may be degraded in the buccal cavity or in the bowel so as to release a therapeutic agent in a controlled manner. Alternatively, therapeutic agents have been released at the skin surface using a multilayered patch that has an adhesive surface associated with a drug containing polymer matrix, and a backing support. Patches have been designed for use in transdermal delivery or topical delivery of drugs and have also been used as wound dressings in which the presence of a therapeutic agent is optional.

Patches utilize polymer matrices for containing therapeutic agents. These polymers are generally synthetic polymers. However, a naturally occurring polycationic polysaccharide polymer, chitosan, has been used in sustained release formulations of therapeutic agents (Thacharodi and Rao; Biomaterials 16 (1995) 145-148). Chitosan is difficult to purify and is commonly contaminated with proteins. Therefore, an adhesive layer formed from acrylates is laminated to the chitosan to form the interface between the body and the patch. Another naturally occurring polymer that has been used in patches is protein. Collagen derived from domestic mammals is most commonly used for this purpose. Just as with chitosan, a separate adhesive layer is recommended for the collagen laminate (EP 0 518697A2). In addition to collagen, the plant protein, gliadin from wheat, has been used in the delivery of superoxide dismutase (WO 96/21462) where gliadin was used as a film and was not incorporated into a laminate.

Patches provide an advantage over oils and creams because delivery of the therapeutic agent may be targeted more precisely to the area of concern, thereby providing improved efficiency at reduced cost.

The plant extracts which comprise aromatherapeutic agents are known as essential oils, and have a history of popular use for a variety of properties, which depending on the source of the extract, include antiseptic, soothing, skin revitalization,

relief of sinus congestion, and general tonic qualities. At present, aromatherapy is effectuated by addition of an aromatic material to massage oil, bath oil, candle wax, pillow stuffing, or to a device such as a vaporizer or a diffuser. These methods of aromatherapy are time consuming or cumbersome, requiring the presence either of an attendent masseuse, or of a piece of non-portable equipment.

Summary of the Invention

It would be desirable to deliver the benefits of aromatherapy by means of a lightweight disposable portable device. A suitable delivery system for the compounds used in aromatherapy may provide the benefits of the treatment at increased convenience and reduced cost.

Accordingly, an embodiment of the invention provides a method for treatment of a condition of an epithelium of the subject, wherein the condition is selected from the group consisting of inflammation, insect bite, allergic reaction, burn, sun burn, eczema, edema, acne, dry skin, oily skin, malodor, abrasion, incision, and bruise, the method comprising: applying proximate to the epithelium of the subject a device for cosmetic aromatherapy treatment of a subject, including an aromatherapeutic composition in a polymeric matrix, the device having a skin adhesive.

Another embodiment of the invention is a method for the cosmetic treatment of a condition of a subject to alleviate a condition selected from the group consisting of fatigue, sinus headache, edematous eyelids, attraction of insects, localized tension in small muscles, and depression, the method comprising: applying proximate to the epithelium of the subject a device for cosmetic aromatherapy treatment of a subject, including an aromatherapeutic composition in a polymeric matrix, the device having a skin adhesive.

Further embodiments of these methods are the aromatherapeutic composition comprising one or more of an essential oil extracted a portion of a plant selected from the group consisting of whole flowers, petals, bark, leaves, twigs, whole fruit, fruit rind, seeds, roots, sap, and resins. Further in these methods, the plant is selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, camphor, carrot, cedar, chamomile, camomile matericaria, chamomile roman, cinnamon,

citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime, mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang. More preferably in these methods, the plant is selected from the group consisting of: aloe vera, almond kernel, basil, bergamot, camphor, chamomile, cypress, eucalyptus, geranium, grapefruit, lemon, peach kernel, peppermint, rosemary, sandalwood, and tea tree.

A further aspect of these methods is that the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 20% of the total on a weight basis, in an amount that is about 0.1 to 10% of the total on a weight basis, and even further, the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 5% of the total on a weight basis.

According to these methods, the polymeric matrix is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a natural polymer. A natural adhesive polymer in these methods is one or more of the polymers selected from the group consisting of a shellac, a chitin, a chitosan, a cellulose, an acacia gum, a carrageenan, a plant latex, a gum arabic, a tragacanth gum, a ghatti gum, a karaya gum; a xanthan gum, a cyclodextrin, a gellan gum, and a plant prolamine. Preferably, the plant prolamine is one or more of the polymers selected from the group consisting of wheat gliadin, corn zein, and barley hordein. A synthetic adhesive polymer used in embodiments of the invention is one or more of the polymers selected from the group consisting of an acrylic, a synthetic rubber, and a silicone based polymer.

An embodiment of the devices of an embodiment of these methods comprises a support substrate. The support substrate is selected from at least one of the group consisting of a backing support and a release liner. The backing support is selected from

the group consisting of paper, cellophane, polyethylene, polyester, polyurethane, polyvinyl chloride, polyamide, fabric, and metal foil. The release liner is selected from the group consisting of polyvinyl chloride, polyester, polyvinylidene chloride, polystyrene, polyethylene, and paper.

An embodiment of the methods here include a device having the shape of a facial mask. The device is maintained proximate to the skin for about 5 minutes to 24 hours.

Another embodiment of the invention is a composition for cosmetic aromatherapy, comprising an essential oil in a polymeric matrix in a container with a suitable vehicle, such that upon delivery of the composition from the container and application to the skin of a subject, evaporative loss of the vehicle from the composition results in formation of a film. A composition according to this embodiment includes the polymeric matrix comprising a mixture of a polymer phase, an active ingredient phase, and an alcohol phase.

The container is selected from the group consisting of an aerosol can, an atomizer, a disposable pouch, a jar with a manual pump, a dropper bottle, and a deformable tube. The essential oil is extracted from a portion of a plant selected from the group consisting of whole flowers, petals, bark, leaves, twigs, whole fruit, fruit rind, seeds, roots, sap, and resins. The plant is selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, camphor, carrot, cedar, chamomile, camomile mataricaria, chamomile roman, cinnamon, citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime, mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang. More particularly, the plant is selected from the group consisting of: aloe vera, almond kernel, basil, bergamot, camphor, chamomile,

cypress, eucalyptus, geranium, grapefruit, lemon, peach kernel, peppermint, rosemary, sandalwood, and tea tree.

An embodiment of the composition comprises one or more additional agents. Other optional agents include one or more selected from the group consisting of: an anti-irritant, a cleansing agent, an antiseptic, a colorant, a pigment, a filler, an antioxidant, a moisturizer, a skin reconditioning agent, a vitamin, a nutritional supplement, an anaesthetic agent, a cosmetic agent, and a therapeutic agent that is not an aromatherapeutic agent. The additional agent can comprise plant polar lipids, for example, ceramides.

Another aspect of an embodiment of the invention is a device for cosmetic aromatherapy treatment of a subject, comprising an aromatherapeutic composition in a polymeric matrix, the device having adhesive properties for the skin of the subject. The aromatherapeutic composition comprises one or more of an essential oil extracted a portion of a plant selected from the group consisting of whole flowers, petals, bark, leaves, twigs, whole fruit, fruit rind, seeds, roots, sap, and resins. The plant is selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, carrot, cedar, camomile, camomile mataricaria, camomile roman, camphor, cinnamon, citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime, mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang.

In an embodiment of the device, the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 20% of the total on a weight basis, in an amount that is about 0.1 to 10% of the total on a weight basis, for example, about

0.1 to 5% of the total on a weight basis, further for example, about 0.2 to 1% on a weight basis. The adhesive properties are conferred by device components which are selected from the group consisting of an adhesive polymeric matrix, and a polymeric matrix that is laminated to an adhesive layer. The adhesive polymeric matrix is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a natural polymer. A natural adhesive polymer is one or more of the polymers selected from the group consisting of a shellac, a chitin, a chitosan, a cellulose, an acacia gum, a carrageenan, a plant latex, a gum arabic, a tragacanth gum, a ghatti gum, a karaya gum; a xanthan gum, a cyclodextrin, a gellan gum, and a plant prolamine. The plant prolamine is one or more of the polymers selected from the group consisting of wheat gliadin, corn zein, and barley hordein.

A device that is an embodiment of the invention can further comprise a support substrate, for example, the support substrate is selected from at least one of the group consisting of a backing support and a release liner. In an embodiment of the device having a backing support, the backing support is selected from the group consisting of paper, cellophane, polyethylene, polyester, polyurethane, polyvinyl chloride, polyamide, fabric, and metal foil. In an embodiment of the device having a release liner, the release liner is selected from the group consisting of polyvinyl chloride, polyester, polyvinylidene chloride, polystyrene, polyethylene, and paper. In an embodiment of the device having both a release liner and a backing support, the backing support is polyester and the release liner is silicone coated polyester.

A device that is a preferred embodiment has the shape of a facial mask. A device in various embodiments is maintained in contact with the skin from for about 5 minutes to 24 hours. A device can treat of a condition of an epithelium of the subject, for example, the epithelium that is the epidermis. The condition is selected from the group consisting of inflammation, insect bite, allergic reaction, burn, sun burn, eczema, edema, acne, dry skin, oily skin, malodor, abrasion, incision, and bruise. In another embodiment of the device, the aromatherapeutic agent may benefit the subject by reduction of a condition selected from the group consisting of fatigue, sinus headache, edematous eyelids, attraction of insects, localized muscular tension, and depression.

Brief Description of the Drawings

Figure 1 is a representation of a cross section of a three layered patch, in accordance with an embodiment of the invention, having a backing support which is a film (1), an adhesive polymeric layer in which is included an aromatherapeutic agent (2) between (1) and a release liner (3), shown in the embodiment of the figure with a central cut to facilitate manual grasp.

Figure 2 is a representation of a cross section of a three layered patch, in accordance with an embodiment of the invention, wherein (4) is a non adhesive porous polymeric matrix containing an aromatherapeutic agent and any additional optional agents, (5) is an adhesive layer, and (6) is a release liner shown in the embodiment of the figure here with a tab at one end. The peripheral adhesive layer (5) of this embodiment is shown to underlay and surround the centrally-located polymeric matrix containing the aromatherapeutic agent.

Detailed Description of the Specific Embodiments

A novel patch composition is provided that, in a preferred embodiment, includes an active agent, where the active agent is oil-based dispersion of a chemical compound or a mixture of chemical compounds that is derived from or consists of extracts from any of flowers or a flower part such as petals, bark, leaves, twigs, roots, seeds, resins, derivatives, components, analogs, or other plant extract that is commonly utilized to provide aromatherapeutic relief. This relief may effectuate a feeling of well being and relaxation, following relief from a condition such as a sinus headache, small muscle tension, puffy edematous eyelids, or insect bites. An enhancing agent may be included in the patch as desired. Other optional agents include one or more of: an anti-irritant, a cleansing agent, an antiseptic, a colorant, a pigment, a filler, an antioxidant, a moisturizer, a skin reconditionaing agent, a vitamin, a nutritional supplement, an anaesthetic agent, a cosmetic agent, and a therapeutic agent that is not an aromatherapeutic agent.

Definitions

As used in this description and in the accompanying claims, the following terms shall have the meanings indicated unless the context otherwise requires.

The term "patch" includes a two-, three-, four-, and multi-layer laminated device, and a film-forming gel for dermal (topical), for local delivery of an aromatherapeutic

substance and for additional agents. The devices of the invention are directed to treatment of skin conditions. Active substances may be incorporated into the film or device for targeting to a local site so as to promote healing. The size and shape of the composition or dosage unit may be designed to fit the site of application.

The term "aromatherapeutic agent" includes any therapeutic agent obtained from a higher plant, as described in U.S. patents 5,620,695, and 5,716,928, and PCT patent application WO 97/01348, and 21 C.F.R. §182.

The term "essential oil" (EO; see U.S. patent 5,716,928, which is hereby incorporated by reference herein) means a predominately volatile material isolated from an odorous, single-species botanical source or a part of a plant as described supra. A widely used process for extraction is steam distillation, although dry distillation and solvent extraction, particularly ethanol extraction, are used. A botanical source is odorous if a volatile component can be detected by any animal, not just a human subject. A large variety of EOs are available commercially (U.S. patent 5,716,928) because of use in food, and can be purchased, for example, from a variety of suppliers (Alexander Essentials, London; www.aroma-sales@alexr.co.uk; Graham Sorenson, Wakes, US). Many EOs are recognized in 21 C.F.R. §182 by the FDA as GRAS (generally regarded as safe).

The term essential oil refers both to the entire EO as obtained from the plant, as well as to fractions of the EO or to individual components. The EO obtained from leaves of the herb oregano, for example, contains both thymol and carvacrol, with certain wild species (*O. hyrtum* and *O. heracleotium*) having a higher content than domestic cultivars (PCT 97/01348). Further, EO from oregano *O. heracleotium* from Crete contains a greater ratio of carvacrol to thymol than other strains, and anti-bacterial and anti-fungal properties are ascribed to oregano EO having these compounds. As EO is defined here, the EO from oregano includes thymol and carvacrol.

The term "natural" refers to an EO or other product derived by a single or few manipulations from an organismal source.

The term "therapeutic agent" includes any compound known in the art to be used for the treatment of a certain disorder.

The term "cosmetic agent" includes any compound known in the art to be used for

improving skin appearance, integrity, and health.

The term "film" is a composition formed from a substantially homogeneous dispersion, comprising a polymeric matrix and an aromatherapeutic agent in a vehicle comprising solvents and other additives as described herein, wherein the composition occupies a three dimensional volume in which one dimension is significantly smaller than the other two dimensions. The film may be precast or formed in situ (at the target site).

The term "selected site" is defined here and in the claims as any part of the epithelial surface of the subject.

The term "topical" is defined here and in the claims as the mode of administration of the active substances such that the active substance is targeted superficially to a selected site.

The term "small muscle" includes the muscles of the head, neck, hands and feet.

The term "safe " as used herein, means that no significantly undesirable effects are induced upon the application of the composition.

A "subject" is an adult male or non-pregnant female human in need of aromatherapy.

A "pressure-sensitive adhesive" (PSA) is any device or composition that can adhere to skin of a subject with the application of gentle pressure. The PSA compositions used in embodiments of the invention do not require pre-wetting or moisturizing, rather only light manually-applied pressure, similar to that for applying a disposable adhesive bandage, is required for adhesion to skin. Additional forms of manipulation and palpation are within the scope of the embodiments of the invention. The device is formulated and packaged in a ready-to-use format, having a protective disposable release liner which protects the surface of the PSA during storage and which is removed and discarded at the time of use.

A "support substrate" means a backing support or a release liner upon which a polymeric matrix layer comprising an aromatherapeutic agent can be deposited.

The patch may be applied to the face or to any other particular body part where aromatherapy is desired. Delivery of the active agent may continue from as little as about one minute, from about five minutes to one hour, or from about one hour to four hours,

from about six hours to overnight, and in another embodiment of the invention, for at least about 24 hours.

A patch device used herein can be formed from a polymer matrix layer containing the active agent, the polymeric matrix layer itself being adhesive, or the polymeric matrix may be placed at one face, adjacent and laminated to an adhesive layer and optionally a release liner, the second opposite face being in contact with a backing support. Thus, the patch device can be a multilayer, a three-layer, a two-layer device. Alternatively, the patch can be formed from a polymeric matrix which is applied as an aerosol or a gel, and forms a patch which is a single layer film.

The size and shape of the device having an aromatherapeutic dosage unit may be designed to fit the site of application. The size, shape and color of the device can be fanciful, or can be manufactured for minimal contrast with a shade of skin, and in the case of the embodiment that is a gel forming polymeric matrix, can be transparent or translucent.

A preferred shape of a patch having a support substrate is a facial mask, comprising an oval shape having cut-outs for the eyes. The oval shape of the mask may have extended areas to cover portions of the cheeks or the forehead of the subject. One or more of the embodiments of the patch device can be applied to the forehead and temple regions, around the ocular cavity, and along the lower mandible, as necessary for a therapeutic effect.

A polymeric matrix of a patch may be formed from entirely natural materials to form a device that is an embodiment of the invention, for example, one or more aromatherapeutic agents may be mixed with a polymeric matrix which is a plant protein such as a prolamine (gliadin from wheat or zein from corn), and a plant polar lipid such as a ceramide, to form a dispersion. The dispersion is for example cast on a nonsiliconized side of a polystyrene film, which can be laminated on a siliconized polyester sheet, which sheet can have previously been coated with a thin layer of an adhesive. An entirely natural sheet, such as cellulose, can be used. A release liner can be placed against a surface of the polymer layer on the surface opposite to the backing film, as in Example 1. Alternatively, a gel as in Examples 2-3 is dispensed from a container, is applied to skin, and dries to form a film.

Aromatherapeutic agents

The aromatherapeutic agent is one or more of an essential oil extracted from a plant selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, carrot, cedar, camomile, camomile mataricaria, camomile roman, camphor, cinnamon, citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime, mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang.

The aromatherapeutic composition can be added to the polymeric matrix in an amount that is about 0.1 to 10% of the total on a weight basis, preferably the essential oil is added to the polymeric matrix in an amount that is about 0.1 to 5% on a weight basis. The essential oil can be added to the polymeric matrix in an amount that is about 0.2 to 1% on a weight basis.

Because of individual sensitivities to various extracts, it is recommended that a small sensitivity test be performed prior to use of the devices and compositions that are embodiments of the invention be applied to skin of the face. The sensitivity test comprises removal of release liner, if present, followed by application of a patch or a portion of a patch or a sample of a gel to the skin of the inside of the elbow of the subject. The patch device or the gel is maintained in contact with the skin for about 24h, and the area is checked for sensitivity after that time.

Polymeric matrices

In accordance with an embodiment of the invention, a biodegradable system in the form of a flexible disk is provided which may be applied directly to the surface of the skin. The flexible disk may include an effective dose of an aromatherapeutic agent. The

flexible disk includes a backing material and a release liner, which is removed prior to application to the skin.

According to an embodiment of the present invention, the disk can be made of materials known in the art to possess filmogenic properties. The filmogenic materials can preferably be any of synthetic origin, such as a polyvinyl chloride derivative or another adhesive; or the materials can be of semi-synthetic origin such as any of different cellulose derivatives. The filmogenic materials can be of natural origin, such as a polymer from an animal, for example chitin or chitosan from a crustacean exoskeleton, or from a plant, such as a gum, for example, xanthin gum, karaya gum, or a plant resin, for example mastic (for example from *Pistachia lentiscus* var. Chios), or a plant protein such as from wheat or corn, such as a prolamine protein. The prolamine protein can be a zein from maize, a hordein from barley, or a gliadin from wheat. The filmogenic plant protein polymer can be a mixture of proteins, for example, a mixture of wheat gliadins.

In one embodiment, the disk is flexible and contains PVP at a concentration of less than 50%, in which embodiment the PVP is a pressure-sensitive adhesive. In another embodiment, the disk is rigid and requires application to a wet surface, in which embodiment PVP at a higher concentration, for example 90-95%, is a filmogenic material.

Synthetic polymeric matrices

The polymeric matrix illustrated in the devices of Figure 1 (2) and Figure 2 (4), which is adjacent to the backing layer shown in Figure 1 (1), can be made of synthetic materials such as acrylics, synthetic rubber, silicone, cellulosics, paper or other suitable materials that may have pressure sensitive adhesive properties and adhere to the skin directly as in the patch of Figure 1, or through a peripheral adhesive as in the patch of Figure 2. The polymeric matrix can be at least one layer of the adhesive-conferring substance or substances, and may contain the aromatherapeutic agent and additional ingredients. The polymeric matrix is generally composed of more than one layer. The thickness of this polymeric matrix is in the range of 0.5 to 30 mils (a mil is one-thousandth of an inch) or more preferably 0.5 to 6 mils.

The polymeric matrix can be made of inert materials which further are biologically and topically acceptable and compatible with the active substances therein.

Preferably, topically acceptable polymers with adhesion properties may be acrylic-based polymers such as the GELVA® series (Monsanto, St. Louis, MO) and the DURO-TAK® series (National Starch, Bridgewater, NJ); synthetic rubber-based polymers also obtained from National Starch; and silicone-based polymers such as BIO-PSA X7-4302 SILICONE PSA sold by Dow Corning.

Natural polymeric matrices

In another embodiment, natural adhesive polymers can be used including plant polymers exemplified by polysaccharides such as cellulose and cellulose derivatives; cyclodextran; gums such as acacia gum; seaweed extracts such as a carrageenan; a natural latex; an exudate gum such as gum arabic (mastic gum), tragacanth gum, ghatti gum, and a karaya gum; gums produced by a microbial growth and fermentation such as xanthan gum; a gellan gum; and by a protein or a mixture of proteins such as a plant prolamine derived for example from a cereal plant (e.g., corn zein, wheat gliadin) and other compounds known in the art.

According to the invention, any member of the gliadin type of prolamines, or any member of any prolamine group may be used including any selected chemical form of gliadin as obtained during purification. Alternatively, a mixture of different types of gliadins may be used. These natural polymers can be used alone, or in combinations, or in conjunction with synthetic polymers. The plant prolamines may be prepared in combination with plant polar lipids to form homogeneous dispersions that form an adhesive matrix layer. They can also be combined with other additives to improve their physicochemical and mechanical properties.

In an embodiment of the invention, a natural polymer of animal origin may be used as an adhesive polymer, such as a polymer derived from an invertebrate such as chitosan and a chitosan derivative, a chitin, and a shellac.

Additional agents which are optional components

The optional components of natural or synthetic origin, known to one of ordinary skill in the art, added to the polymeric adhesive matrix of embodiments of the device of the invention include: a skin anti-irritant, a cleansing agent, an antiseptic, a colorant, a pigment, a filler, an antioxidant, a cosmetically active ingredient such as a keratolytic agent, a moisturizer, a humectant, a skin reconditioning agent, a vitamin, a nutritional

supplement, and a skin penetration enhancer.

Examples of antiseptics include: an alcohol such as ethyl alcohol, isopropyl alcohol, phenyl alcohol, and the natural antiseptic tea tree oil.

Examples of natural or chemical moisturizers include: a preparation of vegetal ceramides such as Ceramide II (obtained from Quest International, Ashford, Kent, England), hyaluronic acid, an essential fatty acid preparation, a collagen, a lipid, a phospholipid, castor oil, sorbitol, glycerol, a glycol, a glycol derivative, and a glyceride, etc.

Examples of vitamins include: vitamin A, vitamin A palmitate, β-carotene, ascorbic acid (vitamin C), ascorbyl palmitate, tocopherol (vitamin E), tocopheryl acetate (vitamin E acetate), vitamin K, and vitamin F (glyceryl linoleate and glyceryl linolenate).

Examples of skin-conditioning ingredients include: a natural extract of any of aloe (for example, *Aloe vera*), *Camellia sinensis* (green tea), camomile, cucumber, corn flower, orange peel, dog rose hip; a marine extract such as from seaweed, kelp, and algae; rice bran oil, wheat germ oil, avocado oil and almond oil; or a chemical composition including an α-hydroxy acid such as glycolic acid, lactic acid, malic acid, and citric acid; a β-hydroxyl acid such as salicylic acid, a polymeric hydroxylic acid, and a ketoacid; and a β-glucan, panthenol, an anthocyanidin, a phytic acid, and an amino acid such as glycine, proline, lysine and leucine.

In addition to an aromatherapeutic agent, which can be present in the range of up to about 20% of the total weight of the composition, the ranges of optional additives, one or more of which may be present in the compositions in weight per cent can be: a skin anti-irritant, up to about 10.0 %; a cleansing agent, up to about 10 %; an antiseptic, up to about 10%; a colorant, up to about 5.0 %; a filler, up to about 30 %; an antioxidant, up to about 5%; a cosmetically active ingredient such as a moisturizer, a skin reconditioning agent, a vitamin, and a nutritional supplement, up to about 20 % for each; a humectant, up to about 10 %; a pigment, up to about 5 %; a keratolytic agent, up to about 10 %; and a skin penetration enhancer, up to about 10 %.

In various embodiments, the ranges of ingredients of the compositions in weight per cent can be: the adhesive polymer, about 30-90%; aromatherapeutic agent, about 0.1-20%; the plasticizing agent, about 5-60%; and optionally, the skin anti-irritant, about 0.5-10%; the cleansing agent, about 1.0-10%; the antiseptic, about 0.1-10%; the colorant,

about 0.1-5.0%; the filler, about 5-30%; the antioxidant, about 0.5-5%; the cosmetically active ingredient such as a moisturizer, a skin reconditioning agent, a vitamin, a nutritional supplement, about 0.5-20%; and the skin penetration enhancer, about 0.5-10%.

Method of manufacturing

The active ingredients and other additives (if used) are added to the synthetic polymer solution, and the mixture is stirred at ambient temperature until all the ingredients have dissolved. The mixture is allowed to stand for several minutes for removal of air bubbles.

The adhesive mixture is formulated into a patch system as follows. Using an appropriate coating device (square tool steel Multi Clearance Applicator, BYK Gardner) with a 5 or 10 mil casting gap, a layer of adhesive mixture was coated onto a siliconized polyester film and dried in an oven at 76 to 78 °C for 15 to 18 min. A breathable polyurethane film (Bertek Medfilm 390) was then laminated onto the adhesive film. The system was then delaminated and further coated with an easy release siliconized polyester film (REXAM Release).

A pressure-sensitive adhesive (PSA) matrix layer of the device having the PSA and other ingredients can have a thickness of about one to 10 mil, preferably a thickness of 2 to 5 mil, more preferably a thickness of 2.5 mil, even more preferably a thickness of 3.5 mil. The backing support can have a thickness of 0.5 to 10 mil, preferably a thickness of 3 to 5 mil. The release liner can have a thickness of 0.5 to 10 mil, preferably a thickness from 3 to 5 mil. The entire device can have a thickness of 3 to 50 mil, for example, can be 4, 8, 12, 16, 20, or 24 mil thick.

The laminated sheet can be cut into a plurality of devices using a stamp-type cutter, or by rotary die cutting, both techniques known to one of ordinary skill in the art. Embodiments of devices of the invention can be in the shape of rectangles ("strips"), circles, circular sectors, and other regular or irregular shapes. A device can have an area of from about 5 to 100 sq. cm., for example, from 5 to 25 sq. cm., from 5 to 30 sq. cm., from 20 to 50 sq. cm., from 5 to 200 sq. cm., and from 10 to 250 sq. cm. A suitable shape for a device is bat-shaped, for example, of dimension approximately 3 by 8 cm., about 20 to 24 sq cm, for release of muscular tension from a particular area of the face, such as the forehead, temples, bridge and sides and base of the nose, and at the sides of

the mouth.

A device for application to another area of the skin, for example, to the chin, can have a smaller dimension, for example, about 2.8 by 6.5 cm, and have a concomitantly smaller surface area, for example, about 12, 15, or 18 sq cm. A tab lacking a pressure-sensitive adhesive matrix layer can extend from the device at one of the longer axes. The user of the device can be directed to cut the strip into smaller shapes for ease of application to an isolated plug in an inaccessible location, such as a plug located in a narrow groove, for example, behind an ear, or in a crease of the nose. A preferred embodiment is a facial mask, having cut-out sections corresponding to the location of the eyes. A mask can extend in a wide "ear piece" to treat the temples, and extend to include the forehead and cheeks.

Film forming polymeric matrices

A formulation and method for the delivery of aromatherapeutic active substances to human subjects as a quick drying film forming gel may overcome the problems of slow release, and of sensitization and irritation associated with other topical patches.

In one embodiment, the formulation of the invention includes an aromatherapeutic agent in a patch which is a water based film-forming material wherein the film is formed upon application of the formulation to a selected site of the human body. In a preferred embodiment of the present invention the specific formulation can form a gel when sprayed on the skin. The composition can be manufactured as a commercial product in an appropriate device/apparatus for application of the composition to the skin of the subject. The amount of the composition that is delivered by the device to the skin can contain an effective amount of the one or more of the active substances in the composition. The gel is formed directly on the site of application after the composition is sprayed or otherwise applied, and when dry the gel forms a film on the skin. The film can be easily removed with water or can be peeled off.

Components of the film-forming gel are found in three phases, Phase A, Phase B, and Phase C (see Tables 2 and 3).

A "spray container" includes any of an aerosol container, e.g., having a gaseous propellant which is a carrier for an active ingredient such as a medicament, and a container having a mechanical pump, for example, an atomizer or other device for normal

use. An aerosol container (see for example, U.S. Patent Nos. 5,234,140 and 5,746,354) with the composition described herein can have a propellant which is a compressed gas that is non-toxic to a human subject in the quantity released by opening of a valve in an apical (top) position of a container with manual force. A gas propellent can be generated *in situ*, for example, CO_2.

A "jar having a manual pump" includes a container capable of using compressed air produced by manual depression and release of a movable piston, which imparts to the compressed air a volume of the composition described herein for delivery to the skin of the subject.

Preparation of the composition

In a preferred embodiment, the preparation of the gel comprises mixing the ingredients of phase B with those of phase A under a condition of continuous agitation. To this mixture the ingredients of phase C are added. The whole preparation is maintained in a sealed container for a period of time, for example, for approximately 6-18 hours, for example, for 12 hours, to allow for removal of the air bubbles. Air bubbles can form and rise to the upper surface of the liquid phase under conditions of ambient pressure and temperature. Removal of air bubbles from the liquid can be accelerated by application of decreased atmospheric pressure or increased temperature, under conditions of pressure and temperature that are compatible with maintenance of the activity and stability of the composition.

The methods and compositions of the present invention are useful for delivery of one or more of an aromatherapeutic and another optional agent.

Delivery

Each formulation can be sprayed upon the skin by any of the methods known in the art, for example, delivering a measured dose using a spray container (see U.S. Patent Nos. 5,618,515 and 5,769,283) as an atomizer attached to a reservoir, or for example, a pump inserted into the aqueous solution such that removal of a restraining cap enables use of first and second fingers to stabilize the vessel containing the reservoir while pushing with the thumb causes delivery of the measured dose. Use of an atomizer does not require pressurization of an additional gas component. The geometry of the

relationship of the pump and the reservoir containing the gel can be of standard description, for example, a separate squeezable pump removably attached to one side, or a top pump which is activated by a push mechanism.

Alternatively, the formulation can be distributed in a spray container which is a pressurized container such as an aerosol can, having the gel solution and a propellent gas, such that pressing a cap allows for release of the formulation carried by the propellent gas. The propellant gas can be compressed air, nitrogen, nitrous oxide (NO), carbon dioxide (CO_2), an inert gas such as argon or helium, a fluorocarbon, sulfur hexafluoride, dimethyl ether or other gas known to one of ordinary skill in the art of spray delivery to be non-toxic and biocompatible in the small quantities necessary for propellant function.

EXAMPLES

EXAMPLE 1: A topical aromatherapy patch containing natural components gliadin and ceramide

The preparation of a patch containing an aromatherapeutic agent in a natural adhesive is as follows. Gliadin powder (272 g; a mixture of wheat prolamine supplied by Inocosm, France) and ceramide powder (12 g; Laboratoires Serobiologiques, France) is added to 604 g of a hydroethanolic solution (50% ethanol in water) to form a dispersion. Glycerol (33g; purity 99%) and sorbitol (78 g; purity 70%) are added to the dispersion. The mixture is placed in a water bath at a temperature for example of 46°C (temperature in the range of 42-48°C is suited for this purpose) and stirred vigorously to obtain a substantially homogeneous dispersion. The dispersion is allowed to cool at ambient temperature with gentle stirring to form a gel having a viscosity of 700-1500 gm/cm.sec (cPoise).

This gel may be formed into a film by spreading or spraying the gel on a surface to permit it to dry. Alternatively, the gel may be used to form a laminate as follows.

Step (1). A first laminate is manufactured consisting of a backing film, a synthetic adhesive matrix and a release liner. A layer of an adhesive matrix, for example, a synthetic adhesive, for example Duro-Tak 87-2353, is cast onto a backing film such as a siliconized polyester film, using a coating device (square tool Multi-clearance Applicator; BYK Gardner, USA) with a 5 mil (about 130μm) casting gap. The resulting two-layer laminate is dried in an oven at 70-75°C for 15-18 minutes, and a low density

polyethylene film is added on to the surface of the adhesive matrix.

Step (2). A second laminate is manufactured consisting of a release liner and layer of the gliadin/ceramide dispersion containing one or more aromatherapeutic agent and other components listed in Table 1. Using a 5 mil (about 130μm) casting gap, a layer of gliadin/ceramide dispersion prepared in step 1 is coated onto the non-siliconized side of a polystyrene film using the Multiclearance Applicator, and dried in an oven at 60-62°C for 10-12 minutes.

Step (3). The release liner on the first laminate is discarded and the exposed adhesive layer is brought into contact with the gliadin/ceramide dispersion surface of the second laminate to form the multi-layer laminate to be cut by the following method into patch devices for use on a subject. The release liner is passed through a Flexomaster 1B (Allied Gear-Netherlands) and circular patches of 0.5 inch (about 1.3cm) diameter are cut, leaving the release liner intact, with perforations to be separated by the end user into individual patches.

Table 1. Composition of the mixture of Example 1

COMPONENT	QUANTITY, % by weight
Gel of step (1)	89.08
Aromatherapeutic agent	10.00
Phenonip® *	0.45
Potassium sorbate	0.05
DL-α-topcopherol	0.42

*Phenonip® is a solution of fine ester of *p*-hydroxybenzoic acid dissolved in phenoxyethanol, supplied by Nipa Laboratories Ltd., U.K.

EXAMPLES 2-5. Gel forming aromatherapeutic compositions with polyvinyl alcohol adhesive.

The formulations of Examples 2 and 3 are shown in Table 2, and of Examples 4 and 5 in Table 3. Phase A contains the synthetic adhesive polyvinyl alcohol A and polyvinyl alcohol B. Phase B contains the aromatherapeutic agent, i.e., the essential oil, and water-soluble active ingredients and water. Humectant ingredients which are miscible with water, such as propylene glycol can be added, as can other solvents such as

ethanol. The aromatherapeutic agent and optional ingredients in phase B. Phase C in these examples contains absolute ethanol at about 15%, and optional components that are more soluble in ethanol than water.

The compositions are formulated in the vehicle of solvents as indicated, such that delivery from a container such as a disposable pouch, forms a gel as a result of rapid evaporative loss of the vehicle on the skin of the subject. The gel can be applied to localized sites such as the forehead, the neck, the wrists, to insect bites, and to other areas in need of aromatherapy. The gel remains in contact with the skin, providing aromatherapy.

Table 2. Compositions of formulations for Examples 2 and 3

Phase	Component	% Amount (on a wei basis)	
		Ex. 2	*Ex. 3*
A	Polyvinyl alcohol A	7.04	6.99
	Polyvinyl alcohol B	4.53	4.50
	Deionized water	58.05	57.61
B	Aromatherapeutic agent	1.93	1.91
	Deionized water	6.22	6.17
	Propylene glycol		4.00
	Butylene glycol	4.00	
	Chlorhexidine digluconate	0.19	0.96
	Optivegetol	5.79	5.74
	Biopure 100	0.24	0.24
C	Nipagin M	0.10	0.10
	Salicylic acid	0.96	0.96
	Ethanol absolute	14.95	14.83

Table 3. Compositions of formulations for Examples 4 and 5

Phase	Component	% Amount (on a wet basis)	
		Ex. 4	*Ex. 5*
A	Polyvinyl alcohol A	7.50	7.50
	Polyvinyl alcohol B	4.70	4.70
	Sodium disulfite	0.10	
	Deionized water	58.80	56.80
B	Aromatherapeutic agent	2.00	2.00
	Deionized water	6.45	6.45
	Propylene glycol	4.00	
	Optivegetol		6.00
	Biopure 100	0.25	0.25
C	Nipagin M	0.10	0.10
	Oxynex 2004	0.10	0.10
	Sodium disulfite	0.10	
	DL-α -tocopherol	1.00	1.00
	Hydroquinone	2.00	2.00
	Ethanol absolute	13.00	13.00

What is claimed is:

1. A method for treatment of a condition of an epithelium of a subject, wherein the condition is selected from the group consisting of inflammation, insect bite, allergic reaction, burn, sun burn, eczema, edema, acne, dry skin, oily skin, malodor, abrasion, incision, and bruise, the method comprising:

applying proximate to the epithelium of the subject a device for cosmetic aromatherapy treatment of a subject, including an aromatherapeutic composition in a polymeric matrix, the device having a skin adhesive.

2. A method for the cosmetic treatment of a condition of a subject to alleviate a condition selected from the group consisting of fatigue, sinus headache, edematous eyelids, attraction of insects, and small muscle localized tension, the method comprising:

applying proximate to the epithelium of the subject a device for cosmetic aromatherapy treatment of a subject, including an aromatherapeutic composition in a polymeric matrix, the device having a skin adhesive.

3. A method according to any of claims 1 and 2, wherein the aromatherapeutic composition comprises one or more of an essential oil extracted a portion of a plant selected from the group consisting of whole flowers, petals, bark, leaves, twigs, whole fruit, fruit rind, seeds, roots, sap, and resins.

4. A method according to claim 3, wherein the plant is selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, camphor, carrot, cedar, chamomile, camomile mataricaria, chamomile roman, cinnamon, citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime,

mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang.

5. A method according to claim 4, wherein the plant is selected from the group consisting of: aloe vera, almond kernel, basil, bergamot, camphor, chamomile, cypress, eucaluptus, geranium, grapefruit, lemon, peach kernel, peppermint, rosemary, sandalwood, and tea tree.

6. A method according to any of claims 1 and 2, wherein the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 20% of the total on a weight basis.

7. A method according to claim 6, wherein the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 10% of the total on a weight basis.

8. A method according to claim 7, wherein the polymeric matrix is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a natural polymer.

9. A method according to claim 8, wherein the natural adhesive polymer is one or more of the polymers selected from the group consisting of a shellac, a chitin, a chitosan, a cellulose, an acacia gum, a carrageenan, a plant latex, a gum arabic, a tragacanth gum, a ghatti gum, a karaya gum; a xanthan gum, a cyclodextrin, a gellan gum, and a plant prolamine.

10. A method according to claim 9, wherein the plant prolamine is one or more of the polymers selected from the group consisting of wheat gliadin, corn zein, and

barley hordein.

11. A method according to claim 8, wherein the synthetic polymer is one or more of the polymers selected from the group consisting of an acrylic, a synthetic rubber, and a silicone-based polymers.

12. A method according to claim 8, wherein the polymeric matrix contains in addition one or more agent selected from the group consisting of: an anti-irritant, a cleansing agent, an antiseptic, a colorant, a pigment, a filler, an antioxidant, a moisturizer, a skin reconditionaing agent, a vitamin, a nutritional supplement, an anaesthetic agent, a cosmetic agent, and a therapeutic agent that is not an aromatherapeutic agent.

13. A method according to claim 12, the device further comprising a support substrate.

14. A method according to claim 13, wherein the support substrate is selected from at least one of the group consisting of a backing support and a release liner.

15. A method according to claim 14, wherein the backing support is selected from the group consisting of paper, cellophane, polyethylene, polyester, polyurethane, polyvinyl chloride, polyamide, fabric, and metal foil.

16. A method according to claim 14, wherein the release liner is selected from the group consisting of polyvinyl chloride, polyester, polyvinylidene chloride, polystyrene, polyethylene, and paper.

17. A method according to claim 16, wherein the release liner is siliconized.

18. A method according to any of claims 1 and 2, the device having the shape

of a facial mask.

19. A method according to claim 18, wherein the device is maintained proximate to the skin for about 5 minutes to 24 hours.

20. A composition for cosmetic aromatherapy, comprising an essential oil in a polymeric matrix in a container with a suitable vehicle, such that upon delivery of the composition from the container and application to the skin of a subject, evaporative loss of the vehicle from the composition results in formation of a film.

21. A composition according to claim 20, wherein the polymeric matrix comprises a mixture of a polymer phase, an active ingredient phase, and an alcohol phase.

22. A composition according to claim 21, wherein the container is selected from the group consisting of a disposable pouch, an aerosol can, an atomizer, a jar with a manual pump, a dropper bottle, and a deformable tube.

23. A composition according to claim 22, wherein the essential oil extracted from a portion of a plant selected from the group consisting of whole flowers, petals, bark, leaves, twigs, whole fruit, fruit rind, seeds, roots, sap, and resins.

24. A composition of claim 23, wherein the plant is selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, camphor, carrot, cedar, chamomile, camomile mataricaria, chamomile roman, cinnamon, citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime, mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma

rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang.

25. A composition according to claim 24, wherein the plant is selected from the group consisting of: aloe vera, almond kernel, basil, bergamot, camphor, chamomile, cypress, eucaluptus, geranium, grapefruit, lemon, peach kernel, peppermint, rosemary, sandalwood, and tea tree.

26. A composition according to claim 25, comprising one or more additional agents.

27. A composition according to claim 26, comprising at least an agent selected from the group consisting of an anti-irritant, a cleansing agent, an antiseptic, a colorant, a pigment, a filler, an antioxidant, a moisturizer, a skin reconditionaing agent, a vitamin, a nutritional supplement, an anaesthetic agent, a cosmetic agent, and a therapeutic agent that is not an aromatherapeutic agent.

28. A device for cosmetic aromatherapy treatment of a subject, comprising an aromatherapeutic composition in a polymeric matrix, the device having adhesive properties for the skin of the subject.

29. A device according to claim 28, wherein the aromatherapeutic composition comprises one or more of an essential oil extracted a portion of a plant selected from the group consisting of whole flowers, petals, bark, leaves, twigs, whole fruit, fruit rind, seeds, roots, sap, and resins.

30. A device according to claim 29, wherein the plant is selected from the group consisting of: aloe vera, almond kernel, angelica, anise, apricot kernel, avocado, basil, bay, benzoin, bergamot, birch, black pepper, bois de rose, borage, cajeput, carrot,

cedar, chamomile, camomile mataricaria, chamomile roman, camphor, cinnamon, citronella, clary-sage, clove, coriander, corn, cumin, cypress, dill, eucalyptus, eucalyptus lemon, eucalyptus peppermint, eucalyptus radiata, evening primrose, fennel, frankincense, geranium, ginger, grapefruit, grapeseed, hazelnut, hops, hyssop, immortelle, inula odorata, jasmine, jojoba, juniper, lavender, lemon, lemon grass, lime, mace, mandarin orange, marjoram, melissa, myrrh, neroli, niaouli, nutmeg, olive, orange, oregano, palma rose, parsley, patchouli, peach kernel, peanut, peppermint, petitgrain, pimento, pine, ravensara, red thyme, rose, rose bulger, rose maroc, rosemary, sage, sandalwood, sesame, soya, spearmint, sunflower, sweet almond, tagetes, tangerine, tea tree, thyme red, valerian, vetiver, violet, wheat germ, wintergreen, yarrow, and ylang-ylang.

31. A device according to claim 30, wherein the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 20% of the total on a weight basis.

32. A device according to claim 31, wherein the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.1 to 10% of the total on a weight basis.

33. A device according to claim 32, wherein the aromatherapeutic composition is present in the polymeric matrix in an amount that is about 0.2 to 5% on a weight basis.

34. A device according to claim 28, wherein the adhesive properties are selected from the group consisting of an adhesive polymeric matrix, and a polymeric matrix that is laminated to an adhesive layer.

35. A device according to claim 34, wherein the adhesive polymeric matrix is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a natural polymer.

36. A device according to claim 35, wherein the natural adhesive polymer is one or more of the polymers selected from the group consisting of a shellac, a chitin, a chitosan, a cellulose, an acacia gum, a carrageenan, a plant latex, a gum arabic, a tragacanth gum, a ghatti gum, a karaya gum; a xanthan gum, a cyclodextrin, a gellan gum, and a plant prolamine.

37. A device according to claim 36, wherein the plant prolamine is one or more of the polymers selected from the group consisting of wheat gliadin, corn zein, and barley hordein.

38. A device according to claim 35, wherein the synthetic adhesive polymeric matrix consists of one or more selected from the group consisting of an acrylic, a synthetic rubber, and a silicone-based polymers.

39. A device according to claim 35, further comprising a support substrate.

40. A device according to claim 39, wherein the support substrate is selected from at least one of the group consisting of a backing support and a release liner.

41. A device according to claim 40, wherein the backing support is selected from the group consisting of paper, cellophane, polyethylene, polyester, polyurethane, polyvinyl chloride, polyamide, fabric, and metal foil.

42. A device according to claim 40, wherein the release liner is selected from the group consisting of polyvinyl chloride, polyester, polyvinylidene chloride, polystyrene, polyethylene, and paper.

43. A device according to claim 40, wherein the backing support is polyester and the release liner is silicone coated polyester.

44. A device according to claim 28 having the shape of a facial mask.

45. A device according to claim 28, wherein the device is maintained in contact with the skin for about 5 minutes to 24 hours.

46. A device according to claim 45, for treatment of a condition of an epithelium of the subject.

47. A device according to claim 46, wherein the epithelium is the epidermis.

48. A device according to claim 47, wherein the condition is selected from the group consisting of inflammation, insect bite, allergic reaction, burn, sun burn, eczema, edema, acne, dry skin, oily skin, malodor, abrasion, incision, and bruise.

49. A device according to claim 45, wherein the aromatherapeutic agent may benefit the subject by reduction of a condition selected from the group consisting of fatigue, sinus headache, edematous eyelids, attraction of insects, and small muscle localized tension.

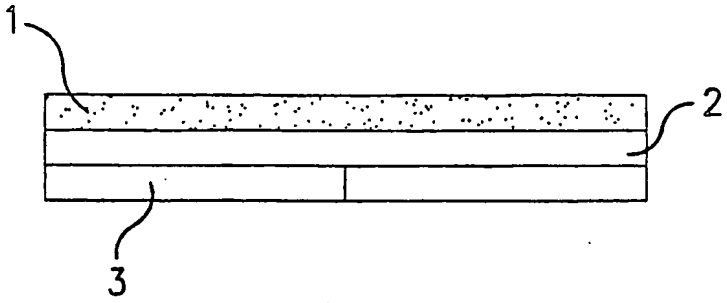

FIG. 1

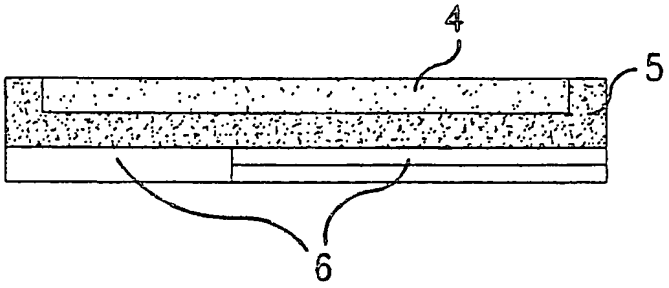

FIG. 2

INTERNATIONAL SEARCH REPORT

Int. ..tional Application No
PCT/US 99/21580

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/70 A61K9/12 A61K35/78

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 456 745 A (ROREGER MICHAEL ET AL) 10 October 1995 (1995-10-10) column 16 -column 17; examples 23,24	1,3-9, 11-17, 19, 28-36, 38-43, 45-49
X	US 4 681 635 A (STIEFEL WERNER K ET AL) 21 July 1987 (1987-07-21) examples claims	20-26
X	FR 2 147 246 A (BRISTOL MYERS CO) 9 March 1973 (1973-03-09) page 24; example 18	20-27

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 March 2000	29/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Boulois, D

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 20 11 235 A (HEIMBACH R. ET AL) 14 October 1971 (1971-10-14) page 2; claims 1-3	1,3-9, 19-27
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X	WO 91 15117 A (BASIC BIO SYSTEMS INC) 17 October 1991 (1991-10-17) page 8, line 13 - line 26 page 30, line 10 - line 25 page 33, line 5 - line 24	20
X	WO 92 06701 A (HUFFSTUTLER M CONRAD JR) 30 April 1992 (1992-04-30) page 4, line 16 - line 21 page 5, line 10 - line 35 page 13; examples C3,,D1	1,3,28, 29,34, 35,45-48
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X	GB 1 122 796 A (GIRARDIERE G.) page 1, line 75 -page 2, line 32 page 3; examples 5-7	1,3,4, 20,28-30

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	SANTUS G C ET AL: "TRANSDERMAL ENHANCER PATENT LITERATURE" JOURNAL OF CONTROLLED RELEASE,NL,ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, vol. 25, no. 1 / 02, 27 May 1993 (1993-05-27), pages 1-20, XP000361364 ISSN: 0168-3659 page 11 ---	28-30
A	KENJU SUGIBAYASHI ET AL: "POLYMERS FOR TRANSDERMAL DRUG DELIVERY SYSTEMS" JOURNAL OF CONTROLLED RELEASE,NL,ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, vol. 29, no. 1/02, 1 February 1994 (1994-02-01), pages 177-185, XP000433662 ISSN: 0168-3659 the whole document ---	1-49
P,X	WO 99 17738 A (LAVIPHARM LAB INC) 15 April 1999 (1999-04-15) page 16 -page 18; example 4 page 20; example 9 page 21 -page 23; example 11 -----	1,3-43, 45-49

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/21580

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Remark: Although claims 1-19 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-49

In view of the large number of alternative solutions to the obvious desirable treatment of the condition of an epithelium and the corresponding compositions and devices, and in view of the wording of the claims as filed (e.g. "aromatherapy"), it is impossible to determine the matter for which protection is sought. Accordingly, the application fails to comply with the requirements of Article 6 PCT, first sentence, and fails to comply with the requirements of clarity and conciseness of Article 6 PCT, second sentence. Moreover, the present claims relate to an extremely large number of possible alternatives for each component (conditions, essential oils, polymers, supports, release liners) which particular combinations have not been supported by the description, because they were not explicitely disclosed in the present application (Article 6 PCT).
As it is even not clear what could be the inventive concept underlying the invention, a restriction of the search to the general concepts of the application was necessary, namely film forming compositions or adhesive compositions comprising aromatherapy actives and their therapeutic use. However, this search already resulted in the citation of 11 documents covering all claims. Only the most relevant documents were selected and cited. The search could not be performed for the huge number of particular combinations of feature allowed by the wording of claims 1-49, which are not supported explicitely by the present application.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

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Inter. onal Application No
PCT/US 99/21580

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INTERNATIONAL SEARCH REPORT

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